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18M1/0122

EXAMINER	
MINNIFIELD, N	
ART UNIT	PAPER NUMBER
1817	

DATE MAILED: 01/22/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.

8/468/45

Applicant(s)

Engel et al

Examiner

Missifield

Group Art Unit

1817

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12-16-97.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 12-19 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 12-19 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## DETAILED ACTION

1. Upon further consideration, the finality of the previous Office Action has been withdrawn. The After Final Amendment filed December 16, 1997 is acknowledged and has been entered. Claims 12-15 and 17 have been amended. Claims 12-19 are now pending in the present application. The previous rejections have been withdrawn and the following new ground of rejection has been set forth.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al, Finkenaar (EP 88-308573), Reissman et al and Moore, taken with Sauerbier et al.

Callahan et al teach "...removal of the HF under vacuum, the resin was washed with ether and air dried. The resin was then extracted with 10% HOAc (120 ml), 1% HOAc (120 ml) and water (120 ml). The aqueous extracts were combined, diluted with water and lyophilized to yield 213 mg crude linear peptide. 100 mg crude linear peptide was purified by gel filtration on G-15 with 1% HOAc to yield." (col 13, l. 8-14). The prior art teaches solubilization of heptapeptide in approximately 100-10,000 parts by weight of acetic acid for each part of peptide wherein the peptide is subsequently transferred to water followed by lyophilization. Finkenaar et al teach a method of lyophilizing a decapeptide in the presence of the bulking agent mannitol. Reissman et al discloses the use of cetorelix in a pharmaceutical composition. Moore et al teach the conventional method of lyophilization; the lyophilizing peptides of 3-15 amino acids after solubilization in a sufficient amount of acetic acid to form a solution (cols. 7-8). The prior art teaches the claimed invention except for specifically reciting that the product was a sterile lyophilizates.

However, Sauerbier et al teach the lyophilization of a product for use and that this peptide had been sterilized (abstract; claims). Sauerbier et al teach "...sterile filtration of the solution only occurs immediately before filling into injection jars. This ensure greater microbiological safety than does the of sterile crystallizate." (col. 2). Sauerbier et al teaches that the prepared

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solution is sterilized by filtration using pathogen proof filters conventionally used for this purpose..." (col. 6, l. 41-43).

The claims are directed to a method of preparing a sterile lyophilizates of gel-forming peptide salts by dissolving peptide salts in acetic acid to form a solution, diluting the solution with water, adding a bulking agent, and sterile-filtering the solution, dispensing into vials and lyophilizing the solution.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the method of Callahan et al, the addition of the bulking agent mannitol as taught by Finkenaur with the reasonable expectation of success of making a lyophilizate of cetorelix as taught in Reissmann et al. The prior art teaches the concept of lyophilizing small peptides. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to sterile filter the peptide so that it would be in a sterile for administration to a human; solubilization of peptides after dissolution in acetic acid will result in stabilization of the peptide and therefore greater usefulness in pharmaceutical applications. The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

4. No claims are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula K. Hutzell, Ph.D., can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

January 13, 1998

  
NITA MINNIFIELD  
PRIMARY EXAMINER